REMARKS
Alex M. Azar II
Deputy Secretary, U.S. Department of Health and Human Services
World Panel on Interoperability
eHealth 2006 High-Level Conference and Exhibition
Málaga, Spain

Good afternoon. Thank you Commissioner Reding; it is a great honor to join this panel. This is a sign not only of our personal friendship, but of the deep and abiding collaboration between the United States and the European Union in many areas.

I'm delighted to have this opportunity to talk with you about some of the steps we're taking at the U.S. Department of Health and Human Services to advance health information technology. Commissioner Reding has well stated the business imperative for health information technology. I will not belabor that point. What I want to talk about how is how we see the problem of interoperability and the approaches we're taking to reach solutions.

HHS Initiatives

During his 2004 State of the Union Address, President Bush charged us with the aggressive goal of making electronic health records available to a majority of Americans within ten years.

We believe that the proper realization and implementation of health information technology is key to transforming our health care system. And we believe that much of that transformation will be achieved not by the heavy hand of a government mandate, but by partnership between the government and the free market that aligns the interest of the multiple stakeholders and consumers. Our role as the federal government is to guide and stimulate the process through example, procurement, and policy, not to dictate the process. At HHS, we are involved in several initiatives that will help drive this utilization of health information technology.

To achieve that goal, last fall, Secretary Leavitt chartered and is now chairman of a Federal Advisory body called the American Health Information Community, or simply the Community. The Community is comprised of government officials along with leaders in the free market, and is tasked with making recommendations to Secretary Leavitt on how to achieve interoperable health information flow while maintaining security and respecting patient privacy.

In our mind, interoperability must be the centerpiece of all efforts, because without interoperability, the promise of ehealth will be only a shadow. We believe in using crystallizing events to drive progress.

The Community has identified four areas that offer the most promise for immediate progress on interoperability, and they are working to achieve implementation within the year:

- **Bio-surveillance**—enabling the transfer of standardized and anonymized health data from the point of health care delivery to authorized public health agencies within 24 hours of its collection;
- **Consumer empowerment**—making available a consumer-directed and secure electronic record of health care registration information and a medication history for patients;
- **Chronic care**—allowing the widespread use of secure messaging, as appropriate, as a means of communicating about diagnoses and treatments between doctors and patients outside of the office setting; and
- **Electronic health records**—assuring that comprehensive laboratory information is available electronically through standardized, secure interfaces to all authorized caregivers who use electronic health records.

In addition to interoperability, we and the Community have four other areas we must solve to realize President Bush's goal. We need:

1. Harmonized standards,
2. We need a process for certifying to consumers that the health I.T. products they buy are interoperable and standards compliant,
3. We need to develop the National Health Information Network over which these records will pass and exist, and
4. We need to address adoption of health I.T.

Standards Harmonization
Many different companies in the U.S. have invested millions of dollars in state-of-the-art health I.T. systems. Unfortunately, not many companies have been investing in systems that can communicate with one another. In order to overcome this problem, we are working to develop and implement a process for achieving a widely accepted and useful health I.T. standard for vocabulary, messaging, and implementation that will support interoperability among all products using electronic health information.

Intimately related to interoperability and standards is **Compliance Certification**:
Just as many of us rely on publications on the market to give us non-biased evaluations of cars, refrigerators, or toasters before we buy them, consumers and providers of health care desire similar seals of approval for I.T. tools. Last year, we awarded a contract to the Certification Commission for Health Information Technology, or CCHIT, a free market, non-profit organization that developed certification criteria for the various critical functions of an ambulatory electronic health record, or what a doctor in a clinic might need to know about his patients. CCHIT's goal is to create tough, transparent, and meaningful product assessments available to purchasers, regulators, payers, investors and others.

This spring, CCHIT conducted tests of the criteria, and it is now accepting applications for operational certification of ambulatory electronic health records. This organization will enable the market to begin selling certified electronic health record products within just a month or two from now that will be capable of at least the following:

- Making consumers' health information portable, in order to improve the quality of care they receive.
- Supporting clinical decisions to improve the safety of care.
- Maintaining the privacy and security of consumers' health information.

Compliance certification will accelerate adoption of electronic health records by reducing the market's hesitancy.

The CCHIT will then move on to certification of hospital electronic health records and the interoperability of other products, including electronic registration systems that will do away with the medical clipboard as we know it.

NHIN Architecture

Another problem we often find in our health care system is a lack of portability. For example, consumers often depend on employers for health insurance, which can make it difficult for some to transfer jobs or move. Similar challenges exist in health I.T. That's why we are working with multiple health care and health I.T. organizations to develop a Nationwide Health Information Network, or a blueprint for how a generalized network would share information across the country. The resulting architectures will allow health care information to follow consumers throughout their lives, wherever they have need for health care.

Stark-Exemptions and Anti-Kickbacks

And in another major step toward adoption and interoperability, we are removing hurdles and giving providers incentives for e-prescribing and electronic health records by encouraging them to purchase software that advances our vision of health I.T. Through these actions, we're guiding purchasers toward systems that will meet the interoperable standards we're working on developing.

Health I.T. and Hurricane Katrina, Ambulatory EHRs

Finally, I would like to share with you some lessons on health information technology we learned in the aftermath of Hurricane Katrina. As we worked to recover, we saw a great need for electronic health records. People who lived in and around New Orleans had their entire medical histories erased overnight, as flooding washed away their paper records. In the days following the hurricane, it was a serious challenge to get people their right medications. We encouraged and facilitated companies to develop a web-based system in order to meet this problem: KatrinaHealth.Org. This tool helped match people with their prescription information to get them the medications and care they needed. KatrinaHealth.org included more than 25 million prescription records for 1.1 million Gulf Coast residents. It also facilitated the issuing of registration credentials to licensed physicians in 34 states.

KatrinaHealth.Org was so successful that we are now working to develop an efficient deployable ambulatory electronic health record that could be used by first responders anywhere in the case of an emergency. It wouldn't be a full-featured electronic health

record. Rather, it would be another emergency services tool—a standardized set of a very limited number of crucial elements that would be needed in an emergency situation.

Conclusion

President Bush gave us a goal of ten years to make electronic health records available to all Americans, and we are moving very aggressively on a number of elements to meet that goal. By next week, we expect to accept a certification process for ambulatory electronic health records. By next year, we expect to have a certification process for the hospital-based electronic health records systems in place. And the following year, we expect to have a similar certification process for NHIN architectures which will allow standardized networks to be built in the private sector.

I've been meeting with my European counterparts on a number of different issues, and one thing I have learned from my interactions with them is that we communicate too little. Far too often, we struggle with the same issues and have to solve the same problems. We all essentially reinvent the wheel. Now that I've explained a little about how we're moving ahead in the United States on health information technology, I hope we can find opportunities for collaboration and areas where we can share our best practices. Thank you.